Economic Value and Intellectual Property Rights of Microbial Genetic Resources

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論文内容要旨

1. Introduction

Biodiversity on earth has evolved over 3.5 billion years. However, in recent decades, the global economic activities of humans have been eroding natural ecosystems at an accelerated rate, which has been threatening the existence of many species and leading to a rapid loss of biodiversity.

Responding to the global concerns about the rapid loss of biodiversity, the Convention on Biological Diversity (CBD) was agreed in 1992 and came into force in 1993. Its third objective is to pursue the fair and equitable sharing of the benefits arising out of the utilization of genetic resources (CBD, Article 1).

The CBD reaffirmed that the states have the sovereign rights over their biological resources, and the authority to determine access to genetic resources rests with the national governments and is subject to national legislation (Article 15). Consequently, bioprospecting firms are required to conclude an access and benefit-sharing (ABS) agreement with stakeholders in source countries, and have to obtain a prior-informed consent (PIC) from the resource government under the framework of the CBD.

However, many developing countries have not yet introduced national regulations on ABS and PIC. Furthermore, due to the following uncertainties, ABS agreements have been difficult to negotiate and conclude promptly.

- Economic value of genetic resources; The unrealistic expectation as to the value of genetic resource raised in developing countries has the negotiation of ABS difficult to conclude.
- Intellectual property rights (IPRs) on genetic resources; IPRs on genetic resource has been a source of conflict between developing countries and developed countries in international forums. such as the World Trade Organization/Agreement on Trade-related Aspects of Intellectual Property Rights (WTO/TRIPs).

This study aims to clarify the economic value and IPRs on genetic resources, to remove obstacles for resource providers and users to negotiate and conclude ABS agreements promptly, which is necessary to attain the third objective of the CBD. This study focuses on microbial genetic resources used as screening materials for new pharmaceuticals development.

2. Economic value of microbial genetic resources

There were several previous studies on the economic value of plant genetic resources. However, there has been no study on a model to estimate the economic value of microbial genetic resources.

If resource providers and users would share the idea as to the total expected profits derived from the use of microbial genetic resource, it would be very useful for both of them to negotiate ABS agreements. Therefore, this

study developed the following model to estimate the economic value based on expected net profits from pharmaceutical sales.

$$Ve = \sum_{i=0}^{n} \frac{p \cdot a \cdot Ri}{(1+d)^i} \quad (1)$$

Ve: economic value of a microbial sample
p: expected probability of success in developing a new pharmaceutical product
a: expected pharmaceutical companies' net profit ratio to the sales
Ri: expected pharmaceutical sales in the *i*th year
d: discount rate

It is impossible to estimate the value of microbial genetic resources with any precision. However, it is possible to obtain an idea as to their magnitudes. For this reason, this study assumed the following values based on various data in pharmaceutical industry:

- **Expected probability of success**: Currently, there is a wide gap in numbers amongst various reports on the probability of success. It is not guaranteed that the probability on success will continues into the future because it involves many unforeseeable factors. This study assumed that expected probability of success would be between 1/100,000 and 1/1,000,000, based on a report by the Japan Bioindustry Association (1999) and the author's interviews with experts of biological screening.
- **Expected pharmaceutical sales in the *i*th year**: The average annual domestic sales of 62 major pharmaceutical products offered by the top four pharmaceutical companies in Japan were US$153 million in 2003 (Annual reports by Takeda, Sankyo, Yamanouchi and Daiichi).
- **Expected net profits ratio to sales**: The net profits ratio to sales of 17 pharmaceutical companies in Japan was an average of 7.4% during 1994- 2003 (Development Bank of Japan, 2004).
- **Discount rate**: This study assumed the discount rate as 10%.
- **Duration of sales**: Pharmaceutical research and development (R&D) takes an average of 10- 15 years (JBA, 1999). This study assumed that pharmaceutical sales would start from the 16th year and end in the 28th year, assuming that a patent would be filed in the third year and sales would continue until such a patent expires 25 years later.

Using those assumptions, this study calculated the economic value of microbial genetic resources as US$20- 200/strain. This value can be understood as the expected total profits derived from the use of microbial genetic resources that can be shared between resource providers and users in ABS agreements under the context of the CBD.

3. Intellectual property rights on microbial genetic resources

In negotiating ABS agreements, the ownership of property right and IPRs on genetic resources affects the outcome of such a negotiation significantly. Therefore, clarifying property right and IPRs on genetic resources may enable resource providers and users to conclude ABS agreements promptly.

By examining regional and national laws and bioprospecting projects conducted in the past, the followings were clarified:

- Most national legislations in developing countries under the CBD have provided the property rights of genetic resources belong to the nation and/or local communities. The concept of common property on genetic resources has been popular among some of developing countries. However, this ambiguity leads to a legal uncertainty for resource users when accessing to genetic resources in developing countries.

- Microorganisms have been patented in developed countries. Patent is an extremely important instrument for pharmaceutical companies to recover R&D costs on new drug development. However, many developing countries rejected the patentability on living forms, including microorganisms.
- In most bioprospecting projects, resource providers retain the property rights of genetic resources when those resource are transferred to users' countries, while IPRs developed based on those genetic resources may belong to the users.

4. Benefit-sharing

There are a few countries that adopted a numerical standard on the benefit-sharing from bioprospecting projects in their national legislation. Some of bioprospecting projects revealed the figures of benefit-sharing between resource providers and users. There has been no common idea on the fairness and equity on the benefit-sharing on genetic resources.

However, those figures were based on bioprospecting projects mainly focused on plant genetic resources. Therefore, this study developed a model to calculate the value of microbial genetic resources that resource providers can expect to obtain from resource users.

Many pharmaceutical companies, when they purchase microbial genetic resources from resource providers, often offer royalties for such microorganisms on the occasion of product launch. It can be assumed that such royalty rates reflect pharmaceutical companies' willingness to pay (WTP) for microbial genetic resources. Therefore, by using the following model, the value of microbial genetic resources can be estimated as the net present value of total expected loyalty payments:

$$Ve = \sum_{i=0}^{n} \frac{p \cdot r \cdot Si}{(1+d)^i} \qquad (2)$$

Ve: value of a microorganism sample
p: expected probability of success in developing a new pharmaceutical product
Si: expected pharmaceutical sales in the ith year
r: royalty
d: discount rate

- **Royalty**: ten Kate and Laird (1999) reported that the average range of royalties for raw material or early research was 0.5- 2.0%. By inquiring with Japanese pharmaceutical companies, it was revealed that the current royalty rate for biological materials in the pharmaceutical industry is 1% at the maximum. Therefore, this study assumed the royalty rate as 0.5- 1.0%.

For other parameters, this study assumed the same values with the model (1).

The result of the above calculation is US$1- 29/sample. This value can be understood as the market value of microbial genetic resources.

When compared with the total economic value of microbial resources that was estimated with the model (1), the benefit captured by resource providers is estimated to be about one seventh of the total profits.

The objective criteria on the fair and equitable benefit-sharing agreements are very difficult to establish. The CBD provides that the benefit-sharing shall be agreed upon mutually agreed terms (Article 15.7). Therefore, this study does not pursue how to attain the fair and equitable benefit-sharing, but pursue how to change the share of the benefits in ABS agreements between resource providers and users. This study concluded as follows:

- Strengthening the property rights in ABS agreements would change the share of the benefits in favor for resource providers.
- IPRs belong to inventors originally. Co-ownership of IPRs with resource providers is difficult for resource

users to accept. Therefore, strengthening IPRs would change the share of the benefits in favor for resource users.

- Obligatory disclosure of the country of origin/source of genetic resources and an evidence of PIC and ABS agreements in patents application may be an effective measure to enforce the CBD. However, this obligation may cause significant burdens on the current international IPR scheme. This issue should be discussed carefully.
- An international certificate scheme of the country of origin/source of genetic resources may also be a useful instrument to enforce the CBD. However, it is necessary to conduct more study on the practicality and feasibility. It should be noted that microbial genetic resources are difficult to identify. Therefore, the participation of institutes on microorganisms (e.g., biological resource centers (BRCs)) would be necessary.

5. Appropriateness of the estimation

The National Institute of Technology and Evaluation of Japan (NITE) conducted a survey on the economic value of microbial strains that NITE provides to academic and non-academic users. Conjoint analysis was adopted to estimate the WTP of the users. In this survey microbial strains that can be used as screening materials for new pharmaceutical research was estimated as US$34- 92/strain.

The following inequality can be found as a whole among the WTP, the market value and the expected total profits estimated by this study.

Market value (US$1- 29/sample) < WTP (US$34- 92/strain) < Expected total profit (US$20- 200/sample)

Therefore, it can be concluded that this study's estimate was at least not unreasonable.

6. Conclusion

This study established a model to estimate the economic value of microbial genetic resources that can be shared between resource providers and users, and clarified measures to change the share of the benefits in ABS agreements in terms of property rights and IPRs of genetic resources. The result of this study, when disseminated widely, may bring a common understanding between resource providers and users that may enable them to conclude ABS agreements promptly.

This model is the first tentative to estimate the economic value of microbial genetic resources. This model may be used for the subsequent studies, including the followings:

- Economic value of *in situ* microorganisms;
- Economic analysis on BRCs.

However, there are issues to be solved. The legal uncertainties on ABS regulations in developing countries may be discouraging private firms of developed countries from accessing to genetic resources in developing countries.

In order to solve this problem, following issues should be investigated urgently:

- Property rights scheme on genetic resources in developing countries, and;
- National ABS regulations that may promote the access of foreign firms to genetic resources in developing countries.

Those studies, if their results will be disseminated widely, may contribute more to the attainment of the fair and equitable sharing of the benefits derived from the use of genetic resources under the CBD.

論文審査結果の要旨

人類の経済活動により熱帯林等の破壊が進行し、これによる生物多様性の急速な減少が世界的な懸念となったため、1992 年に生物多様性条約（CBD）が成立した。CBD の第 3 の目的は、生物遺伝資源の利用から生じる利益の公正かつ衡平な配分である。しかし、①生物遺伝資源の経済価値の評価方法が確立していないこと、②生物遺伝資源の所有権や知的財産権が明確でないため、生物遺伝資源の提供者と利用者によるアクセスと利益配分（ABS）契約の交渉が容易でないのが現状である。本論文の目的は、CBD の第 3 の目的を実現するため、ABS 契約の交渉の障害となっている①生物遺伝資源の経済価値と②所有権と知的財産権について明らかにすることである。この論文では、多様性が豊かで幅広い産業利用が期待される微生物遺伝資源を対象とし、その利用については市場規模が大きい医薬品への応用に焦点をあてている。

本論文は、全文 7 章からなる。

第 1 章は序論であり、本論文の背景と目的について述べている。

第 2 章では、生物遺伝資源を含めた生物多様性全体の経済価値についての先行研究を述べている。

第 3 章では、生物遺伝資源の経済価値についての先行研究の概要と問題点を述べた後、微生物遺伝資源の経済価値を試算する式を提案している。この式は、新規の医薬品開発のために微生物資源をスクリーニングに用いる現実の研究開発プロセスを基礎として、微生物資源の医薬品への利用から得られる利益全体の経済価値を計算するものである。

先行研究は生物遺伝資源の経済価値の研究は植物資源を対象としたもののみであり、微生物遺伝資源を対象とした経済価値の試算は、本論文が初めてである。しかも、現実の製薬企業における研究開発プロセスを踏まえたものであること、試算した経済価値が資源の提供者と利用者が配分する利益の全体額を試算したことも新規性が認められる。

第 4 章では、生物遺伝資源の知的財産権に関する国際的な場での議論について述べた後、各国の国内法と地域のガイドライン、過去に実施された生物遺伝資源の探索プロジェクトにおいて生物遺伝資源の所有権と知的財産権がどのように規定されているかを述べている。

第 5 章では、生物遺伝資源の利用から生じる利益の配分について、各国の国内法や地域のガイドライン、過去に実施された生物遺伝資源の探索プロジェクトにおいてどのように規定されているかを述べた後、CBD が規定する公正かつ衡平な配分は規範的な事項であり客観的な判断基準を確立することは困難であるため、利益配分を変更する方法について述べている。この研究成果を活用することにより、生物遺伝資源の ABS 契約の交渉は容易となり、CBD の第 3 の目的の達成に寄与するものと考えられる。

第 6 章は、本論文の第 3 章で試算した微生物資源の経済価値の値が妥当であるかどうかを検証するために、本論文とは異なる方法による微生物資源の経済価値の評価結果を比較している。この結果、本論文での試算結果は、別の研究成果の結果とは概ね整合しており、少なくとも相反するものではないことを明らかにしている。

第 7 章は、結論である。

以上要するに本論文は、先行研究では対象とされたことがない微生物資源の経済価値を試算した初めての論文である。また、遺伝資源の利用から生じると見込まれる利益の全体額及び利益配分を変更する方法を明らかにしたことも初めての試みである。この論文は、微生物遺伝資源の経済価値と所有権・知的財産権を明らかにしたものであり、微生物遺伝資源を用いた工学（バイオテクノロジー）の発展に貢献するものと考えられる。また、この研究成果は開発途上国の希少な微生物資源の医薬品等への利用を促進することを通じて先進国も開発途上国も共に利益を得ることにつながり、社会的な貢献は大きいと考えられる。

よって，本論文は博士（工学）の学位論文として合格と認める。